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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,678	12/18/2001	David J. Yang	AH-UTXC:681US	2950

26271 7590 03/26/2003  
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EXAMINER
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FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/26/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/024,678		YANG ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Blessing M. Fubara		1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-125 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-125 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-22, 24-45, 47-68 and 70, drawn to a method of dispensing a therapeutic agent in situ, classified in class 424, subclass 422.
  - II. Claims 1, 23, 46 and 69, drawn to method of dispensing therapeutic agent that further comprises the agents recited in claims 23, 46 and 69, classified in class 424, subclass 9.1.
  - III. Claims 71-91, drawn to a method of providing a slow-release hydrogel composition in situ to tumor, classified in class 424, subclass 484.
  - IV. Claims 92-108, drawn to a kit for treating tumor a tumor in situ, classified in class 424, subclass 400.
  - V. Claims 109-125, drawn to kit for occluding an artery associated with a tumor, classified in class 424, subclass 400.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are capable of supporting different patents within the art.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Invention I differs from inventions II, III, IV and V in that invention I does not contain the detectable contrasting agents of invention II, is not a method of providing slow release hydrogel composition in situ to a tumor as in invention III; the method of invention I dispenses while the kits in inventions IV and V are used to treat tumor and occlude artery associated with tumor respectively.

Invention II differs from inventions II, IV and V in that invention II is not a method of providing slow release hydrogel composition in situ to a tumor as in invention III; the method of invention II dispenses while the kits in inventions IV and V are used to treat tumor and occlude artery associated with tumor respectively.

Invention III differs from inventions IV and V in that invention III dispenses while the kits in inventions IV and V are used to treat tumor and occlude artery associated with tumor respectively.

Invention IV differs from invention V in that invention IV treats tumor while invention V occludes the artery associated with a tumor

4. If applicants elect Group I, applicants are required to further elect a specific method of claim 1 or 24 or 47 and a specific therapeutic agent by electing either a single drug from claims 17, 40 and 63; or a single hormone from claims 18, 41 and 64; or a single gene therapy composition comprising one gene therapy agent from claims 19, 42 and 65; or single radionucleotide from claims 21, 44 and 67; or a single nutraceutical from claims 22, 45 and 68. Furthermore, if applicants elect a vector, applicants are required to further elect a specific vector defined in claims 20, 43 and 66 for classification purposes.

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If applicants elect Group II, applicants are required to further elect a specific detectable identifier.

If applicants elect Group III, applicants are required to further elect a specific agent from a drug, hormone, gene therapy agent, radionucleotide and a nutraceutical.

If applicants elect Group IV, applicants are required to further elect a specific agent from a drug, hormone, gene therapy agent, radionucleotide and a nutraceutical.

If applicants elect Group V, applicants are required to further elect a specific agent from a drug, hormone, gene therapy agent, radionucleotide and a nutraceutical.

5. This application contains claims directed to the following patentably distinct species of the claimed invention: Methods of dispensing a therapeutic agent in situ, method of treating tumor in situ and method of occluding an artery associated with tumor are claimed in Group I; X-ray contrasting agent, MRI contrasting agent, fluorophore and luminophore and combinations thereof are recited as detectable identifiers in Group II; drug, hormone, gene therapy agent, radionucleotide and nutraceutical are therapeutic agents recited in Groups III, IV and V.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 24, 47, 71, 92 and 109 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. A telephone call was made to Melissa L Sistrunk on 03/10/03 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara  
Patent Examiner  
Tech. Center 1600

